



7020-02

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337-TA-1145]

Certain Botulinum Toxin Products, Processes for Manufacturing or Relating to Same and Certain Products Containing Same

Institution of Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that a complaint was filed with the U.S. International Trade Commission on January 30, 2019, under section 337 of the Tariff Act of 1930, as amended, on behalf of Medytox Inc. of South Korea; Allergan plc of Ireland; Allergan, Inc., Irvine, California. Supplements to the complaint were filed on February 12, 2019, February 13, 2019, and February 14, 2019. The complaint alleges violations of section 337 based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain botulinum toxin products, processes for manufacturing or relating to same and certain products containing same by reason of misappropriation of trade secrets, the threat or effect of which is to destroy or substantially injure a domestic industry in the United States.

The complainants request that the Commission institute an investigation and, after the investigation, issue a limited exclusion order and cease and desist orders.

ADDRESSES: The complaint, except for any confidential information contained therein, is available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street, S.W., Room 112, Washington, D.C. 20436, telephone (202) 205-2000. Hearing impaired individuals are advised that

information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205-1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at (202) 205-2000. General information concerning the Commission may also be obtained by accessing its internet server at <https://www.usitc.gov>. The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at <https://edis.usitc.gov>.

FOR FURTHER INFORMATION CONTACT: Pathenia M. Proctor, The Office of Unfair Import Investigations, U.S. International Trade Commission, telephone (202) 205-2560.

SUPPLEMENTARY INFORMATION:

Authority: The authority for institution of this investigation is contained in section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, and in section 210.10 of the Commission's Rules of Practice and Procedure, 19 CFR 210.10 (2018).

Scope of Investigation: Having considered the complaint, the U.S. International Trade Commission, on February 28, 2019, ORDERED THAT –

(1) Pursuant to section 337 of the Tariff Act of 1930, as amended, an investigation be instituted to determine whether there is a violation of subsection (a)(1)(A) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain products identified in paragraph (2) by reason of misappropriation of trade secrets, the threat or effect of which is to destroy or substantially injure a domestic industry in the United States;

(2) Pursuant to section 210.10(b)(1) of the Commission's Rules of Practice and Procedure, 19 CFR 210.10(b)(1), the plain language description of the accused products or category of accused products, which defines the scope of the investigation, is botulinum

neurotoxin products manufactured by Daewoong Pharmaceuticals Co., Ltd., specifically: (1) DWP-450 (prabotulinumtoxinA), variously marketed under the brand names Nabota®, Jeuveau™ and other brand names; (2) products containing or derived from DWP-450; and (3) products containing or derived from the BTX strain assigned the high-risk pathogen control number 4-029-CBB-IS-001 by the Korean Centers for Disease Control and Prevention or the manufacturing process used to manufacture DWP-450;

(3) For the purpose of the investigation so instituted, the following are hereby named as parties upon which this notice of investigation shall be served:

(a) The complainants are:

Medytox Inc.

626 Tehran Road

Gangnam, Seoul

South Korea

Allergan plc

Clonshaugh Business and Technology Park

Coolock, Dublin, D17 E400

Ireland

Allergan, Inc.

2525 Dupont Drive

Irvine, CA 92612

(b) The respondents are the following entities alleged to be in violation of section 337, and are the parties upon which the complaint is to be served:

Daewoong Pharmaceuticals Co., Ltd.

Bongeunsaro 114-gil 12

Gangnam, Seoul, 06170

South Korea

Evolus, Inc.

17901 Von Karman Avenue, Suite 150

Irvine, CA 92614

(c) The Office of Unfair Import Investigations, U.S. International Trade Commission, 500 E Street, S.W., Suite 401, Washington, D.C. 20436; and

(4) For the investigation so instituted, the Chief Administrative Law Judge, U.S. International Trade Commission, shall designate the presiding Administrative Law Judge.

Responses to the complaint and the notice of investigation must be submitted by the named respondents in accordance with section 210.13 of the Commission's Rules of Practice and Procedure, 19 CFR 210.13. Pursuant to 19 CFR 201.16(e) and 210.13(a), such responses will be considered by the Commission if received not later than 20 days after the date of service by the Commission of the complaint and the notice of investigation. Extensions of time for submitting responses to the complaint and the notice of investigation will not be granted unless good cause therefor is shown.

Failure of a respondent to file a timely response to each allegation in the complaint and in this notice may be deemed to constitute a waiver of the right to appear and contest the allegations of the complaint and this notice, and to authorize the administrative law judge and the Commission, without further notice to the respondent, to find the facts to be as alleged in the complaint and this notice and to enter an initial determination and a final determination containing such findings, and may result in the issuance of an exclusion order or a cease and desist order or both directed against the respondent.

By order of the Commission.

Issued: February 28, 2019.

Lisa Barton,

Secretary to the Commission.

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